DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 1, 2015

Biomet Microfixation
Ms. Lauren Jasper
Senior Regulatory Affairs Specialist
1520 Tradeport Drive
Jacksonville, Florida 32218

Re: K143336
Trade/Device Name: Biomet Microfixation OmniMax MMF System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY, DZL
Dated: February 27, 2015
Received: March 2, 2015

Dear Ms. Jasper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Division Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K143336**

Device Name: Biomet Microfixation OmniMax MMF System

Indications for Use: The Biomet Microfixation OmniMax MMF System is indicated for temporary stabilization of mandibular and maxillary fractures to maintain proper occlusion during surgery and for post-operative fracture healing in adults and adolescents (age 12 and older) in whom permanent teeth have erupted.

Prescription Use __xx_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K143336

510(k) Summary

Prepared April 1, 2015

Submitter: Biomet Microfixation
1520 Tradeport Drive
Jacksonville, FL 32218

Contact: Lauren Jasper, Senior Regulatory Affairs Specialist
lauren.jasper@biomet.com
Telephone: (904) 741-9259
Fax: (904) 741-9425

Device Name: Biomet Microfixation OmniMax MMF System

Device Classification:

Product Code	Device Name	Device Classification	Regulation Number	Regulation Description
JEY	Plate, Bone	2	872.4760	Bone Plate
DZL	Screw, Fixation, Intraosseous	2	872.4880	Intraosseous fixation screw or wire

Indications for Use: The Biomet Microfixation OmniMax MMF System is indicated for temporary stabilization of mandibular and maxillary fractures to maintain proper occlusion during surgery and for post-operative fracture healing in adults and adolescents (age 12 and older) in whom permanent teeth have erupted.

Contraindications: 1. Patients with mental or neurological conditions who are unwilling or incapable of following postoperative care instructions; 2. Patients with limited blood supply, insufficient quantity or quality of bone; 3. Foreign body sensitivity; where material sensitivity is suspected, testing is to be completed prior to implantation; 4. Severely comminuted fractures or unstable fractures; 5. Active or latent infection; 6. Patients in whom damage to un-erupted permanent teeth is anticipated.

Device Description: The Biomet Microfixation OmniMax MMF System is composed of metallic plates (arch bars) and locking screws that provide temporary stabilization of mandibular and maxillary bone during fracture healing and/or temporarily maintain a stable occlusion during surgery. Mandibular and Maxillary Fixation (MMF) is achieved through application of fixation plates and locking screws to bone; wire or elastics are then secured around hooks. The arch bar

plate is manufactured from Commercially Pure Titanium; and the locking screws are manufactured from Titanium Alloy (Ti-6Al-4V).

Predicate Devices:
Primary:
K061271, KLS Erich Arch Bar
Secondary:
K122313, Stryker Universal SMARTLock Hybrid MMF System
K040983, Lorenz Self-Drilling IMF Screw

Similarities to Predicate Devices: The predicate and subject devices are metallic implants intended to be used for the temporary stabilization of mandibular and maxillary bone during fracture healing and/or temporarily maintain a stable occlusion during surgery. The subject device combines the technology of the primary predicate (arch bar) with that of reference predicates (bone screws). Primary predicate and subject device consist of an arch bar plate used to achieve MMF when secured by wires or elastics. Subject device is also similar to reference predicate Lorenz Self-Drilling IMF screws by incorporating a screw design with the same thread geometry, material, and similar lengths.

The indications for use and intended use of the subject device and all predicates are similar.

Subject and predicate devices are similar in dimensions; arch bars and plates may be cut to length as needed by patient anatomy. Screw diameters and lengths are similar and the proposed screws do not fall outside of the dimensions set by predicate devices.

Differences to Predicate Devices: The subject device has design differences from the predicate devices which are intended to eliminate the need for interdental wiring of the arch bar for fixation, help approximate the bar in an anatomic position and provide greater screw placement options. The subject device includes an arch bar manufactured from Commercially Pure Titanium and screws manufactured from Titanium Alloy (Ti-6Al-4V). The KLS Erich Arch Bar is manufactured from Stainless Steel.

Non-Clinical Performance Data: All non-clinical performance testing passed according to the acceptance criteria. Testing was conducted as follows:

- Screw – Insertion/Fracture Torque, Bending/Shear, Push-Through
- Plate and Screw Construct Static and Fatigue Testing
- Simulated Use Cadaver Lab

Clinical Performance Data: Clinical testing was not necessary for the determination of substantial equivalence.

Sterilization Information: The implants are provided non-sterile to be sterilized by the end user.

Substantial Equivalence: The predicate and subject devices are metallic implants for the temporary stabilization of mandibular and maxillary bone during fracture healing and/or

temporarily maintain a stable occlusion during surgery. The primary predicate device achieves fixation through the use of an arch bar that is wired to the teeth (interdental wiring). The subject device achieves fixation through the use of an arch bar that is fixated with bone-borne screws.
The indications are considered substantially equivalent because both devices are intended to be used in MMF procedures. The principles of operation are also considered substantially equivalent because both systems include an arch bar as the main component used to achieve MMF closure. This arch bar, in both designs, has hooks spaced across the length of the bar; wires or elastics are wrapped around the hooks of the mandible and maxilla bars to bring the jaws into proper occlusion and maintain this placement until healing has occurred.

The subject device includes an arch bar manufactured from Commercially Pure Titanium and screws manufactured from Titanium Alloy (Ti-6Al-4V). The KLS Erich Arch Bar is manufactured from Stainless Steel. This is substantially equivalent as all materials are standard metals and alloys appropriate for use in dental applications. The materials used in the subject device are identical to those used in reference predicates, where information is known.

The Biomet Microfixation OmniMax MMF System utilizes similar principles of operation of the predicate devices. It has nearly identical intended use, indications for use, material, and technological characteristics similar to the legally marketed predicate devices. It is concluded that the information included in this summary supports substantial equivalence.

	Subject Device: Biomet Microfixation OmniMax MMF System	**Primary Predicate: KLS Erich Arch Bar (K061271)**	**Reference Predicate: Stryker Universal SMARTLock Hybrid MMF System (K122313)**	**Reference Predicate: Lorenz Self-Drilling IMF Screw (K040983)**
Principle of Operation	Metallic implants for the temporary stabilization of mandibular and maxillary bone during fracture healing and/or temporarily maintain a stable occlusion during surgery Mandibular and Maxillary Fixation (MMF) is achieved through application of fixation plates and locking screws to bone; wire or elastics are then secured around hooks	Metallic implants for the temporary stabilization of mandibular and maxillary bone during fracture healing and/or temporarily maintain a stable occlusion during surgery Mandibular and Maxillary Fixation (MMF) is achieved through application of arch bars wired to the teeth with ligature wire; wire or elastics are then secured around hooks	Metallic implants for the temporary stabilization of mandibular and maxillary bone during fracture healing and/or temporarily maintain a stable occlusion during surgery Mandibular and Maxillary Fixation (MMF) is achieved through application of fixation plates and locking screws to bone; wire or elastics are then secured around hooks	Metallic implants for the temporary stabilization of mandibular and maxillary bone during fracture healing and/or temporarily maintain a stable occlusion during surgery Intermaxillary Fixation (IMF) is achieved through application of screws to bone; wire or elastics are secured through relief grooves or holes in the screws
Indications for Use	The Biomet Microfixation OmniMax MMF System is indicated for temporary stabilization of mandibular and maxillary fractures to maintain proper occlusion during surgery and for post-operative fracture healing in adults and adolescents (age 12 and older) in whom permanent teeth have erupted.	The Erich Arch Bar is indicated for use in intermaxillary and maxilla-mandibular fixation.	The Stryker Universal SMARTLock Hybrid MMF System is indicated for the treatment of mandibular and maxillary fractures in adults and adolescents (age 12 and higher) in whom permanent teeth have erupted.	The Lorenz IMF screw is intended for use as a bone screw in temporary fixation of the maxilla and mandible, providing indirect stabilization of fractures of the maxilla and/or the mandible.
Components	Fixation Plate (Arch Bar), Locking Screws	Arch Bar	Fixation Plate (Arch Bar), Locking Screws	IMF Screws

	Subject Device: Biomet Microfixation OmniMax MMF System	**Primary Predicate: KLS Erich Arch Bar (K061271)**	**Reference Predicate: Stryker Universal SMARTLock Hybrid MMF System (K122313)**	**Reference Predicate: Lorenz Self-Drilling IMF Screw (K040983)**
Plate Geometry	Design: Plate with an in-plane bend and 12 slots to accept screws and 12 hooks	Design: Arch Bar sold a bulk length of material that is cut to the length necessary for the patient anatomy; hooks are spaced over the entire length	Design: Straight plate with 9 holes to accept screws and 17 hooks	Not Applicable
Screw Geometry	Design: Self-drilling screws Diameter: 2.0mm Length: minimum 7mm, maximum 11mm	Not Applicable	Design: Self-drilling screws Diameter: 2.0mm Length: minimum 6mm, maximum 8mm	Design: Self-drilling screws Diameter: 2.0mm Length: minimum 5mm, maximum 11mm
Material	Plates: Commercially Pure Titanium Screws: Titanium Alloy, Ti-6Al-4V	Stainless Steel	Plates: Commercially Pure Titanium Screws: Titanium Alloy	Titanium Alloy, Ti-6Al-4V
Sterility	Non-sterile to be sterilized by the end user	Non-sterile to be sterilized by the end user	Non-sterile to be sterilized by the end user	Non-sterile to be sterilized by the end user